November 10, 2005

The Honorable Mike Leavitt Secretary of Health and Human Services US Department of Health and Human Services 200 Independence Avenue, SW Washington, DC 20201

Dear Mr. Secretary,

In your remarks at the October 7 American Health Information Community (AHIC) inaugural meeting, you highlighted the need to establish breakthroughs that deliver near-term results to patients and consumers. We agree there is a great opportunity to make near term progress for interoperability of health information aimed at consumer empowerment using existing standards and technologies. We applaud this direction for AHIC, and wish to work with you to put the puzzle pieces together that will enable a personal health record (PHR) to improve quality and safety of care through greater continuity of patient health information.

In this regard, the undersigned physician membership and national medical associations urge AHIC to recommend the use of the Continuity of Care Record, CCR, standard (American Society for Testing and Materials (ASTM) E2369-05 Standard Specification for the Continuity of Care) as the basis of a national PHR breakthrough project or projects.

The CCR standard is naturally suited to this purpose, while also consistent with longer-term national HIT infrastructural solutions, for the following reasons:

- 1. The CCR standard is a fully-balloted health information technology (HIT) standard, endorsed by multiple physician organizations as well as by a growing number of EHR and PHR vendors who have already integrated the CCR into their products and services. It is therefore 'in the market' and available for use, after more than two years of steady development under the auspices of ASTM International.
- 2. The CCR standard is a *comprehensive* clinical content standard with 16 sections such as patient demographics, encounters, diagnoses, medications, allergies, immunizations, etc. Because these components are all optional, the CCR is well-suited to the use-case of both a partial and a complete PHR, as described in the AHIC breakthroughs. For example, the CCR standard would serve well as the basis of an AHIC PHR focused on immunization record portability and interoperability, or limited to

medications listings, or limited to just the registration (clipboard) information. At some later date, however, these components of PHR data could be assembled into a single more inclusive file for any patient using the same CCR standard format. This extensibility and flexibility is a unique design feature of the CCR standard, and makes it highly valuable as the basis for personal health record interoperability.

- 3. The CCR standard utilizes an extensible markup language (XML) syntax based on World Wide Web Consortium (W3C)-compliant rules used within the general computer industry and is intentionally non-healthcare specific to optimize the use by developers of general computer industry XML tools and skill sets. Use of broad industry-standard XML also assures that the data contained in a CCR file can be expressed in multiple media formats that are friendly to both consumers and providers alike. These include: as a paper document, e.g. PDF or Microsoft Word; as HTML, e.g. in a Web browser; as an XML file on personal storage media, e.g. a USB memory stick; or transmitted to and stored within a remote server or database accessible from the Internet. This multi-purposing capability of the CCR standard will provide wide consumer and provider choice with respect to where and how the data are viewed, reposed (stored), and transmitted, while guaranteeing standardization of data structure at all times.
- 4. The CCR standard will permit interoperable exchange of personal health data between and among disparate EHRs used in medical practices. A national PHR project must utilize a standard for content and format that enables EHRs in physicians' offices, clinics, and group practices to both create (export) and seamlessly import data from PHRs used by patients and consumers. We must avoid creating a situation that poses new workflow and data entry problems during the processes of patient registration and evaluation. Use of the CCR standard will mean that physicians and their office staff will not be put in a position of having to type and re-enter data, which will assuredly be the result if PHRs are permitted to take on a myriad of non-standard, proprietary formats.
- 5. The CCR standard is an open standard free of licensing fees, and is already in the process of both conformance and 'harmonization' with other HIT standards, including the HL7 Clinical Document Architecture (CDA) and National Council on Prescription Drugs Program (NCPDP) Script standards. ASTM's E31.28 Electronic Health Record Subcommittee is working closely with NCPDP to define the new *SIG* extensions to NCPDP Script to support e-prescribing, and discussions are ongoing between ASTM and other standards development organizations (SDO) with respect

Letter to Sec. Leavitt CCR basis for Personal Health Records November 10, 2005 Page 3

to standards for security. ASTM International is a participant in the new American National Standards Institute (ANSI) Healthcare Information Technology Standards Panel (HITSP) program on standards harmonization, and is fully committed to standards harmonization, as are the volunteer members of ASTM E31.28, many of whom are practicing physicians in a wide range of specialties including, but not limited to, family medicine, internal medicine, emergency medicine, pediatrics, and cardiology.

In summary, we urge you and all AHIC members to "not let perfect be the enemy of the good" by taking advantage of the natural fit between the CCR standard and the proposed PHR or component PHR projects that were presented at the first AHIC meeting. While admittedly not fulfilling the vision of "pure interoperability" of health care information systems and their informational stores, the CCR standard is a robust technology that offers a substantial near term opportunity to empower patients and consumers while also serving as a foundational building block upon which to place additional components of the future national health information network.

With very kind regards,

American Academy of Dermatology Association American Academy of Family Physicians

American Academy of Ophthalmology

American Academy of Pediatrics

American College of Emergency Physicians

American College of Obstetricians and Gynecologists

American College of Osteopathic Internists

American College of Osteopathic Family Physicians

American Gastroenterological Association

American Medical Association

American Osteopathic Association

Massachusetts Medical Society

cc: Dr. David Brailer, Office of the National Coordinator for HIT